

**Notice of Allowability**

Applicati n No.

09/747,371

Examiner

Diana B. Johannsen

Applicant(s)

GISH ET AL.

Art Unit

1634

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 30 October 2003.
2. ☒ The allowed claim(s) is/are 32-39.
3. ☒ The drawings filed on 21 December 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- 1 ☒ Notice of References Cited (PTO-892) *(correction of prior 892)*
- 3 ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 5 ☐ Information Disclosure Statements (PTO-1449), Paper No. \_\_\_\_\_
- 7 ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- 2 ☐ Notice of Informal Patent Application (PTO-152)
- 4 ☒ Interview Summary (PTO-413), Paper No. 1103
- 6 ☒ Examiner's Amendment/Comment
- 8 ☐ Examiner's Statement of Reasons for Allowance
- 9 ☐ Other

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Viola T. Kung on October 30, 2003.

The application has been amended as follows:

2. **Cancel** claims 1-6 and 8-31.

3. **Amend** the claims as follows:

32. A method for detecting a breast cancer cell in a patient, the method comprising:

(i) detecting a nucleic acid encoding [an amino acid sequence at least 90% identical to] SEQ ID NO:2 in a sample from the patient, and

(ii) comparing expression levels of the nucleic acid in the sample from the patient to expression levels of the nucleic acid in a normal tissue sample,

wherein an increase in expression of the nucleic acid in the sample from the patient as compared to the normal tissue sample indicates the presence of a breast cancer cell in the patient.

34. The method of claim [32] 33, wherein the nucleic acids are mRNA.

37. The method of claim 32, wherein said detecting [step further comprises] is carried out by using a labeled nucleic acid probe.

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38. The method of claim 32, wherein said detecting [step] is carried out by utilizing a biochip comprising a nucleic acid sequence encoding SEQ ID NO: 2, wherein said nucleic acid sequence is at least 90% identical to SEQ ID NO: 1.

39. The method of claim 32, wherein said detecting [step] is carried out by utilizing a biochip comprising a nucleic acid sequence encoding SEQ ID NO: 2, wherein said nucleic acid sequence is at least 95% identical to SEQ ID NO: 1.

4. **Amend** the paragraph at page 1, after line 8, as follows:

This application is a continuation-in-part of U.S. Patent Application Ser No. 09/525,361 filed March 15, 2000, which is a continuation-in-part of U.S. Patent Application Ser No. 09/453,137 filed December 2, 1999, now abandoned [and this application is a continuation-in-part of international application PCT/US00/06952, filed March 15, 2000; each of which is incorporated herein by reference in its entirety].


5. **Change** the title of the application to:

Methods for detection and diagnosing of breast cancer.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

  
Diana B. Johannsen  
November 1, 2003

  
CARLA J. MYERS  
PRIMARY EXAMINER